

PATENT

Customer No. 22/852

Attorney Dock t No.: 09062/0456

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)

Michel GARRAIT et al.)

Appln. No.: 09/350,152)

Group Art Unit: 1623

Filed: July 9, 1999)

Examiner: T. Oh

For: PROCESS FOR THE
PREPARATION OF
HYDROXYMETHYLBUTYRIC
ACID)**REQUEST FOR RECONSIDERATION**Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In reply to the final Office Action dated August 23, 2002, Applicants respectfully request reconsideration in view of the following remarks.

I. Status of Claims

Claims 15-34 are pending in this application. No amendments have been made in this Response. However, claims 16-34 were amended in the amendment after final filed on December 23, 2002, which applicants have requested entry of in the RCE accompanying this paper.

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II. Rejections Under 35 U.S.C. §103(a)

The Office has rejected claims 15-34 under 35 U.S.C. § 103(a) as obvious over *Suchsland et al.*, U.S. Patent No. 5,847,207, ("*Suchsland*") in view of *Hsu et al.*, U.S. Patent No. 5,856,567 ("*Hsu*").

The Office acknowledges that *Suchsland* differs from the instant invention in that the operation of the first step is not carried out under vacuum. (Office Action of January 15, 2002, at 4). However, the Office alleges the combination of *Suchsland* with *Hsu* cures this defect because *Suchsland* teaches the application of vacuum after the formation of the amide and *Hsu* points out that the rate of nitrile hydrolysis can be reduced by the addition of excess water. *Id.* at 5. Based upon this disclosure, the Office alleges that if one of ordinary skill in the art had the desire to increase the rate of nitrile hydrolysis in the first step of the operation, it would have been obvious for the skilled artisan to have operated the first hydrolyzing step of *Suchsland* under vacuum. *Id.* Applicants respectfully traverse this rejection for the reasons of record as well as the reasons presented below.

The presently claimed invention is a process for the hydrolysis of 2-hydroxy-4-methylthiobutyronitrile (HMTBN) comprising, *inter alia*, hydrating HMTBN in a sulphuric acid medium to produce 2-hydroxy-4-methylthiobutyramide, wherein the molar quantity of sulphuric acid relative to the HMTBN is between 0.6 and 0.88 and the hydration is carried out at a temperature of less than or equal to 60 °C and under vacuum.

As motivation to modify the process of *Suchsland* in order to arrive at the claimed invention, the Office points to *Suchsland*'s teaching of adiabatic evaporation vacuum cooling of the final amide product coupled with a statement in *Hsu* that indicates the rate

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of nitril hydrolysis is reduced by the addition of dilution water. Contrary to the Office's assertions, Applicants respectfully submit that when "viewed as a whole" *Suchsland* in combination with *Hsu* does not teach or suggest operation of the hydration step under vacuum as is presently claimed.

In evaluating a *prima facie* case of obviousness, 35 U.S.C. § 103(a) expressly requires consideration of the claimed invention "as a whole". *In Re Langer*, 465 F.2d 896, 897, 175 U.S.P.Q. 169, 170 (C.C.P.A. 1972). The Examiner must show some motivation for modifying the teachings of the references, and a reasonable expectation of success in doing so. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 733 F.2d 900, 902, 221 U.S.P.Q. 1125, 1127 (Fed. Cir. 1984). In the instant application, the Examiner has failed to establish the required *prima facie* case of obviousness.

Regarding *Suchsland*, the Examiner has noted that the optional introduction of a vacuum is done, if at all, after the formation of the final amide product. That is, vacuum is applied after both the hydration of the nitrile and the hydrolysis of the amide are already completed. As acknowledged by the Office, *Suchsland* simply does not teach or suggest performance of the hydration of the nitrile under vacuum.

Hsu discusses that the nitrile hydrolysis rate is reduced by addition of dilution water, and further discloses that a simple adjustment of residence time in the CSTR is all that is required to minimize residual nitrile. (*Hsu*, col. 5, lines 52-65). Despite the teaching of *Hsu*, the Examiner nonetheless concludes that one skilled in the art would

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recognize that vaporation of excess water vapor would necessarily increase the nitrile hydrolysis rate, even though this is not taught or suggested by *Hsu*. (Office Action, p. 8). Further, the Examiner concludes that a skilled artisan would be motivated to operate the hydrolysis step under vacuum to accomplish this evaporation, even though neither cited reference teaches or suggests such a modification. *Id.* *Hsu* simply does not teach or suggest that execution of the nitrile hydrolysis can be conducted under vacuum to reduce residual nitrile. Quite the contrary, *Hsu* teaches away from the use of a vacuum, stating that the first step should be conducted at or above atmospheric pressure, 0 to 15 psig (1.01 to 2.02 bar) (*Hsu*, col. 8, line 9). Should the Examiner continue to maintain this position, in light of the express teaching away of the art, Applicants respectfully request that he further explain his position.

The skilled artisan would not have been motivated by *Hsu* to modify the process of *Suchsland* by incorporation of cooling under vacuum to reduce excess water and residual nitrile because *Hsu* does not teach use of vacuum or the evaporation of water vapor. Furthermore, *Hsu* clearly discloses that a simple adjustment of residence time in the CSTR is all that is required to minimize residue nitrile.

Hsu emphasized that residual nitrile is significantly reduced simply by ensuring a modest residence time in its nitrile hydrating reactor. No mention of the use of vacuum is made. There is nothing in *Hsu* to motivate and direct one of ordinary skill to combine its teachings with those of *Suchsland* because *Hsu* teaches a satisfactory, simple to implement, and cost effective solution to the residual nitrile problem and there was no apparent disadvantage to *Hsu's* disclosed solution.

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The Examiner suggests that one skilled in the art would be motivated to utilize a vacuum in the hydrolysis step because *Suchsland* already suggests applying a vacuum after the formation of the amide. However, *Suchsland*'s optional vacuum evaporation process step is conducted adiabatically, which would not at all be useful in the nitrile hydration step. (*Suchsland*, col. 5, lines 52-53). In adiabatic evaporation, heat does not enter or leave the system being cooled, that is, no external cooling is applied. Cooling is accomplished by using the available sensible heat to supply the latent heat of evaporation so as to transform a liquid into a gas at a given pressure. It is well known in the art that the nitrile hydration process is very exothermic. (*Hsu*, col. 5, line 10). In fact, to ensure sufficient heat transfer for cooling, *Hsu* recommends conducting the nitrile hydrolysis in a back-mixed, continuously stirred tank reactor. (*Id.*, col. 5, line 11-12). Controlling the nitrile hydration reaction temperature through adiabatic evaporation under vacuum would be extremely difficult because this technique would not be capable of producing the cooling necessary to remove the heat load generated by the highly exothermic reaction, without having a tremendously sized heat sink. As such, one of ordinary skill in the art would not have reasonably expected that implementation of the adiabatic evaporation technique could successfully control the heat load generated during the nitrile hydration. Therefore, there is nothing in *Suchsland* to teach or suggest the desirability of running the nitrile hydration step under vacuum as is presently claimed.

Additionally, when viewed "as a whole", there is simply nothing in the combined teachings of *Suchsland* and *Hsu* to direct or motivate one of ordinary skill in the art to modify the process of *Suchsland* in the manner suggested by the Office. Nothing but

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the present invention discloses execution of the nitrile hydration step under vacuum. It is impermissible hindsight to use the claimed invention as a guide through the maze of prior art references, combining the right references in the right way to so as to achieve the result of the claim invention. See *Grain Processing Corp. v. American Maize-Products Corp.*, 840 F.2d 902, 5 U.S.P.Q.2d 1788 (Fed. Cir. 1988).

Accordingly, a *prima facie* case of obviousness has not been made. Applicants therefore respectfully request the withdrawal of this 35 U.S.C. § 103(a) rejection.

CONCLUSION

In light of the foregoing remarks, Applicants respectfully submit that the pending claims are in condition for allowance. A prompt and favorable action is requested. Please grant any extension of time required to enter this amendment and charge any additional required fees to our deposit account No. 06-916.

Respectfully submitted,

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Date: July 28, 2003

By: 

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